REMARKS

Applicants thank the Examiner for the helpful telephonic interview on September 5, 2007 between Rebekka Noll, Sandra Brockman-Lee and Examiner Schnizer. Amendments to possibly place the claims in condition of allowance were discussed. In addition, the reference "Fusion of influenza virus membranes with liposomes at pH 7.5" Haywood and Boyer, *Proc. Natl. Acad. Sci.* 82:4611-4615 (1985) was mentioned. Applicants respectfully request entry of the Supplemental IDS containing the reference or in the alternative that the reference be placed in the file.

Applicants respectfully request entry of this Amendment and Response and submit that the claim amendments are supported by the claims as originally filed, no further searching is required.

Claim Amendments

Claim 1 has been amended to delete "types of" as suggested by the Examiner. Claim 1 has also been amended to recite "said fusogenic vesicle comprising a first viral fusion protein, wherein the first viral fusion protein is X-31 hemaglutinin (HA) and at least one other viral fusion protein selected from the group consisting of influenza virus, VSV, SFV, Sendai virus, and HIV, wherein the at least one other viral fusion protein causes fusion at a different temperature than X-31 HA." Support for this amendment is found, for example, in claims 1, 6, and 10 as originally filed.

Claims 7, 9, 10 and 13 have been amended to be consistent with claim 1.

Claims 6 and 38 have been cancelled without acquiescing in the propriety of any of the rejections and reserving the right to pursue the claimed subject matter in continuing applications.

Information Disclosure Statement

An IDS was filed on 1/26/07. The Examiner stated in the Office Action dated 3/6/07 that the references in the 1/26/07 IDS were considered. However, the IDS was found non-compliant with 37 CFR 1.98 because some of the citations lacked the title of the journal and/or the volume number of the journal. A corrected IDS 1449 form is submitted concurrently herewith. The corrected IDS lists only those references present on the IDS filed 1/26/07 corrected to include the journal and/or volume number of the journal.

Rejection under 35 U.S.C. §112, Second Paragraph

Claims 1-4, 6, 7, 9-16 and 38 are rejected under 35 U.S.C. §112, second paragraph, for the lack of proper antecedent basis.

Claim 1 has been amended to delete "types of" as suggested by the Examiner. Claims 1-4, 7, and 9-16 satisfy the requirements of 35 U.S.C. §112, second paragraph. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejection under 35 U.S.C. §112, First Paragraph

Claims 1-4, 6, 7, 9-16 and 38 are rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement.

Without acquiescing in the propriety of the rejection, Applicants have amended claim 1 to recite that the fusogenic vesicle comprises a first viral fusion protein, wherein the first viral fusion protein is X-31 hemaglutinin (HA) and at least one other viral fusion protein selected

from the group consisting of influenza virus, VSV, SFV, Sendai virus, and HIV, wherein the at least one other viral fusion protein causes fusion at a different temperature than X-31 HA.

Claims 1-4, 7, and 9-16 meet the requirements of 35 U.S.C. §112, first paragraph because the application teaches that X-31 HA is capable of causing fusion at low temperature and fusion vesicles can be made that comprise X-31 HA and another viral fusion protein from influenza virus or from vesicular stomatitis virus G protein, Semliki forest virus E1 protein, or Sendai virus F protein (see, for example, paragraph [0026]). Withdrawal and reconsideration of the rejection are respectfully requested.

Rejection under 35 U.S.C. §102(b)

Claims 1-4, 7, 9, 11, and 13-16 and 38 stand rejected under 35 U.S.C. §102(b) as being anticipated by Gunther-Ausborn, *et al.* as evidenced by Junankar, *et al*, Blough and Stegman *et al.* The Examiner states that Gunther-Ausborn teaches that "the fusion proteins immunologically active substances are part of the vesicle capsule, and so are considered to be encapsulated." Applicants respectfully disagree.

Claim 1 is drawn to "a fusogenic vesicle encapsulating at least one therapeutic or immunologically active substance." In addition, claim 1 has been amended to recite that the fusogenic vesicle comprises "a first viral fusion protein wherein the first viral fusion protein is X-31 hemaglutinin (HA)" and "the at least one other viral fusion protein causes fusion at a different temperature than X-31 HA."

Claim 1 is novel over the cited references, because Gunther-Ausborn fails to teach all of the elements of claim 1. Gunther-Ausborn fails to teach fusogenic vesicles comprising a first fusion protein, wherein the first viral fusion protein is X-31 hemaglutinin (HA) and at least one

other viral fusion protein selected from the group consisting of influenza virus, VSV, SFV, Sendai virus, and HIV, wherein the at least one other viral fusion protein causes fusion at a different temperature than X-31 HA.

Furthermore, Gunther-Ausborn describes membrane fusion mediated by two types of HA fusion proteins X-47 and A/Shangdong that are functionally coreconstituted in the membrane. (See page 2718, Discussion). According to Gunther-Ausborn, the viral fusion proteins X-47 and A/Shangdong are embedded in a membrane such that at least some portion of the fusion protein is exposed on the outer surface of the membrane. (Page 2716, column 1).

Substances that are embedded in a membrane as taught by Gunther-Ausborn are not "encapsulated" according to the ordinary and customary meaning of the word "encapsulate." The Examiner contends that "[t]he fusion proteins immunologically active substances that are part of the vesicle capsule, and so are considered to be encapsulated." However, the Examiner's interpretation of the meaning of "encapsulate" is inconsistent with the ordinary and customary meaning of the word. The ordinary and customary meaning of the word "encapsulate" is "to enclose in or as if in a capsule." *Webster's Ninth New Collegiate Dictionary*. The ordinary and customary meaning of the root word "enclose" is "to close in: surround." *Id.* The ordinary and customary meaning of the root word "capsule" is "a shell usu. of gelatin for packaging something (as a drug or vitamins); *also*: a usu. medicinal or nutritional preparation for oral use consisting of the shell and its contents." *Id.* Therefore, the ordinary and customary meaning of "encapsulate" is to surround a substance within a shell or capsule. Since the X-47 and A/Shangdong viral fusion proteins of Gunther-Ausborn are embedded in the membrane such that they are exposed on the outer surface of the membrane, they cannot be considered as "encapsulated" by the membrane.

Therefore, claim 1 is novel over Gunther-Ausborn as evidenced by Junankar, *et al*, Blough and Stegman *et al*. Claims 2-4, 7, 9, 11, and 13-16 are dependent upon claim 1 and therefore are also novel over Gunther-Ausborn, *et al.* as evidenced by Junankar, *et al*, Blough and Stegman *et al*. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection under 35 U.S.C. §103(a)

Claims 1, 11, and 12 are rejected under 35 U.S.C. §103(a) as being unpatentable over Gunther-Ausborn *et al* in view of Wheeler and taken with the evidence of Junankar *et al* and Blough.

Claim 1 is drawn to a fusogenic vesicle comprising a first viral fusion protein X-31 hemaglutinin (HA) and at least one other viral fusion protein selected from the group consisting of influenza virus, VSV, SFV, Sendai virus, and HIV and wherein the at least one other viral fusion protein causes fusion at a different temperature than X-31 HA.

As described above, Gunther-Ausborn *et al* teach viral fusion proteins X-47 and A/Shangdong embedded in a membrane where at least some portion of the fusion protein is exposed on the outer surface of the membrane, whereas Wheeler teaches gene delivery.

Claims 1, 11 and 12 are patentable over the combined teachings of Gunther-Ausborn *et al* in view of Wheeler and taken with the evidence of Junankar *et al* and Blough because the combined teachings fail to disclose or suggest every element of the claims. There is no teaching or suggestion in the combined teachings of a fusogenic vesicle comprising a first viral fusion protein, wherein the first viral fusion protein is X-31 hemaglutinin (HA) and at least one other viral fusion protein selected from the group consisting of influenza virus, VSV, SFV, Sendai

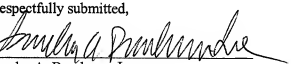
virus, and HIV, wherein the at least one other viral fusion protein causes fusion at a different temperature than X-31 HA.

Therefore, claim 1 is non-obvious over the combined teachings of Gunther-Ausborn *et al* in view of Wheeler and taken with the evidence of Junankar *et al* and Blough. Claims 11 and 12 are dependent upon claim 1. Therefore, claims 11 and 12 are also non-obvious over Gunther-Ausborn, *et al* in view of Wheeler and taken with the evidence of Junankar *et al* and Blough. Withdrawal and reconsideration of the rejection are respectfully requested.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application is respectfully requested. If the Examiner has any questions, the Examiner is invited to call Applicants' representative directly at (617) 526-9617.

Respectfully submitted,



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